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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,132	09/21/2001	Richard G. Sitz	53964US002	5024

32692 7590 09/16/2003

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EXAMINER	
MICHENER, JENNIFER KOLB	
ART UNIT	PAPER NUMBER
1762	7

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/960,132	SITZ ET AL.	
	Examiner	Art Unit	
	Jennifer Kolb Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-21* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-21, drawn to a method of selectively removing volatile components, classified in class 427, subclass 386.

   II. Claim 22, drawn to a method of forming a transdermal drug delivery composition, classified in class 427, subclass 2.31.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together have different modes of operation, functions, and effects. A method of selectively removing volatile components is distinct and unrelated in operation, function, and effect to a method of making a transdermal drug delivery composition.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Brian Szymanski on 7/17/2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-21. Affirmation of this election must be made by applicant in replying to this Office action. Claim 22 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-4 and 6-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garbe et al. (WO 96/08229) in view of Huelsman et al. (5,694,701).
Garbe et al. teach a method of coating a coating formulation onto a first substrate surface of a substrate, wherein the substrate is an adhesive coated sheet or web material in the form of an article such as a tape, patch, or sheet (page 14, lines 25-27). The coating formulation of Garbe comprises a solvent, drugs, and softeners (page 14, lines 5-10). While Garbe does not specifically teach that the drugs and softeners are "volatile" and "liquid", Examiner notes that the drugs and softeners of Garbe (outlined below regarding the relevant dependent claims) are the same as the drugs and

"excipients" (equivalent to softeners) claimed by Applicant. Therefore, the drugs and softeners/excipients are inherently volatile liquids, as required by claim 1.
After coating, Garbe teaches that the substrate is dried (p. 14, line 20).
What Garbe fails to teach is a method of drying.

Huelsman teaches a method of drying a coated web substrate, such as an adhesive-coated web or a tape to remove solvent (abstract; col. 6, line 54; col. 13, line 26 and line 51; col. 14, line 18). The method of Huelsman removes solvent in a controlled fashion, by slowing down the rate of evaporation or stopping the evaporation completely, even in liquid coatings with multiple solvents (col. 11, lines 42-60). Huelsman's method involves positioning the coated substrate requiring solvent removal between a condensing surface and a heating surface, with the coated surface facing the condensing surface (abstract). Figure 2 shows that the heated surface is in thermal contact with the side of the coated substrate opposite the coated surface and condensing surface. The chilled condensing surface temperature is lower than the heating surface temperature (col. 6, line 50).

Since Garbe teaches drying an adhesive coated web, sheet, or tape and Huelsman teaches a method of controllably drying an adhesive coated web or a tape to remove solvent therefrom, Huelsman would have reasonably suggested his drying mechanism in the method of Garbe. It would have been obvious to one of ordinary skill in the art to use the teachings of Huelsman in the method of Garbe to provide Garbe with a

controlled method to remove solvent from his adhesive coated web, sheet, or tape. Because Garbe teaches the use of therapeutic drugs in his coating, which are often temperature-sensitive, it would have been obvious to one of ordinary skill in the art to look to the prior art for a method of controllably removing solvents, such as is taught by Huelsman, in a manner which does not damage or remove the expensive therapeutic agents contained therein.

Because Huelsman teaches a method of solvent removal, the method of Garbe in view of Huelsman would have inherently selectively removed solvent from the coated substrate, as required by claim 1, and left the drugs and excipients behind, as required by claim 2. It would have been obvious to one of ordinary skill in the art to select temperatures such that the drugs and excipients are not damaged or removed during the drying process in order to maintain the integrity and usefulness of the adhesive-coated substrate. If there is some difference in outcome between Applicant's claims and the method detailed by Huelsman it must be due to some process limitations not currently claimed by Applicant.

Regarding claims 3 and 4, it is Examiner's position that selection of heating surface temperatures is within the skill of an ordinary artisan intending to optimize results for evaporating solvent. One of ordinary skill would select an appropriate temperature for a given solvent within a given composition.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 6, Huelsman teaches that the condensing surface may be 5 cm from the coated web or closer, such as less than 1 cm (col. 7, line 9; col. 12, lines 58). This range overlaps the range claimed by Applicant.
Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Huelsman's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Huelsman teaches condensing the solvent vapor on the condensing surface, forming a condensate and removing the condensate while it remains in a liquid state for collection, as required by claims 7-8 (col. 7, lines 33-43; col. 8, lines 23-30; col. 9, lines 1-20).

Regarding claim 9, Garbe teaches the use of ethyl acetate, methanol, acetone, ethanol, isopropanol, or toluene, among others, as solvent, as required by claim 9 (page 14, lines 5-10) .

Regarding claims 10-11, Garbe teaches the use of nitroglycerin and scopolamine (page 12, lines 15 and 31), as required by claim 11. These drugs must inherently be liquid, as

required by claim 10, just as they are in Applicant's claims because Applicant claims a "liquid drug", such as "nicotine, nitroglycerin, or scopolamine". Additionally, the drugs of Garbe are supplied in a matrix "substantially free of solid", indicating a liquid form of the drugs.

Regarding claims 12-14, Garbe teaches the use of softeners matching the list of excipients required by claims 13-14 (page 9). Therefore, Garbe's softeners are liquid "excipients" required by Applicant in claim 12.

Regarding claim 15, Garbe teaches the use of testosterone as the drug of his formulation (page 12, line 21).

Regarding claim 16, Garbe teaches that the coated web substrate may be a transdermal drug delivery composition (throughout).

Regarding claims 17-19, as outlined above, the transdermal composition of Garbe may include an adhesive, such as an acrylate (abstract).

Regarding claims 20-21, the substrate of Garbe includes a release liner and backing film (page 13, line 22; page 14, line 20).

Allowable Subject Matter

12. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The closest prior art fails to teach a temperature gradient along the heating surface, in combination with the requirements of the independent claim, such as is outlined in claim 5.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wick is cited for teaching the desirability of removing solvents from transdermal patches without removing the other volatile ingredients, such as drugs, and that simple heat evaporation detrimentally destroys or removes volatile drugs. Von Falkenhausen teaches that simple heat evaporation of solvents from transdermal patches often removes an unacceptable level of active substances and auxiliaries. These references are cited to show the need for controlled methods of solvent removal from coated transdermal patches.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
September 8, 2003